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45,943
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PATENT
Confirmation no. 3131
Atty. Dkt. No. 087147-0494 (new)
Atty. Dkt. No. 087147-0450 (old)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re reissue application of: U.S. Pat. No. 6,348,481, issued February 19, 2002

Applicants: Yoshiyuki INADA, et al.

Title: PHARMACEUTICAL COMPOSITION FOR ANGIOTENSIN II-MEDIATED DISEASES

Appl. No.: 10/781,263

Filing Date: 02/19/2004

Examiner: Deborah C. Lambkin

Art Unit: 1626

AMENDMENT AND REPLY AFTER NOTICE OF APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper responds to the Final Office action dated August 22, 2005, concerning patent application no. 10/781,263. It is timely, because it was filed within two-months of the Notice of Appeal dated February 22, 2006.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this document. **Remarks** begin on page 6 of this document. Please amend the application as follows:

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NOTICE: THIS APPLICATION IS A REISSUE APPLICATION, AND (i) *Amendments in reissue applications do not fall under 37 CFR § 1.121:* "Any amendment to the description and claims in reissue applications must be made in accordance with § 1.173." *37 CFR § 1.121(i).* **Accordingly, do not send a notice alleging that this paper fails to comply with 37 CFR § 1.121.**

1. (Four times amended) A method for the [prophylaxis or] treatment of angiotension II-mediated disease in a mammal in need thereof which comprises administering an effective amount of [at least one of]

(±)-1-(cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate,

2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or

[2-ethoxyl-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]]-1H-benzimidazole-7-carboxylic acid,]

2-ethoxy-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or a pharmaceutically acceptable salt thereof, in combination with an effective amount of furosemide.

2. (Thrice Amended) A method according to claim 1, wherein the disease is hypertension, cardiac insufficiency, ischemic peripheral circulation [disorders] **disturbances**, myocardial ischemia, vein insufficiency, progressive cardiac insufficiency after myocardial infarction, diabetic nephritides, nephritis, arteriosclerosis, hyperaldosteronism, dermatosclerosis, glomerulosclerosis, renal insufficiency, **diseases of** central nervous system [diseases], sensory [disorders] **disturbances** [Alzheimer's disease], deficiency of memory, depression, amnesia and senile dementia, anxiety neurosis, catatonia [or indisposition], glaucoma, or intraocular high [pressure] **tension**.

4. A pharmaceutical composition which comprises at least one of :

(±)-1-(cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate,

2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or

2-ethoxy-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or a pharmaceutically acceptable salt thereof, in combination with a compound having diuretic activity or a compound having calcium antagonistic activity.

5. The composition of claim 4, in which the compound having diuretic activity is a member selected from the group consisting of amiloride, chlorothiazide, hydrochloride, benzthiazide, ticrynafen, acetazolamide, aminophylline, cyclothiazide, cyclopentiazide, methyclothiazide, benthylhydrochlorothiazide, penfluthiazide, ethiazide, hydroflumethiazide, polythiazide, chlophenamide, chlorthalidone, cyclothiazide, bendroflumethiazide, meticrane, tripamide, metrazone, quinethazone, bumetanide, mefruside, azosemide, ethacrynic acid, sodium ethacrynate, piretanide, spironolactone, potassium canrenoate, quinethazone and triamterene.

6. The composition of claim 4, in which the compound having calcium antagonistic activity is a member selected from the group consisting of diltiazem hydrochloride, teloridine hydrochloride, nicardipine hydrochloride, varnidipine hydrochloride, flunarizine hydrochloride, verapamil hydrochloride, cinnarizine, nisoldipine, nitrendipine, nifedipine, nilvadipine, felodipine, nildipine, nimodipine, penidipine and benidipine.

7. A method for treatment of angiotensin II mediated diseases in a mammal in need thereof which comprises administering an effective amount of at least one of

(±)-1-(cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylate,

2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or

2-ethoxy-1-[[2'-(2,5-dihydro-5-oxo-1,2,4-oxadiazol-3-yl)biphenyl-4-yl]methyl]-1H-benzimidazole-7-carboxylic acid, or a pharmaceutically acceptable salt thereof, in combination with a compound having diuretic activity or a compound having calcium antagonistic activity.

8. The method of claim 7, in which the angiotensin II-mediated diseases is selected from the group consisting of hypertension, cardiac insufficiency, ischemic peripheral circulation disturbances, myocardial ischemia, vein insufficiency, progressive cardiac insufficiency after myocardial infarction, diabetic nephritides, nephritis, arteriosclerosis, hyperaldosteronism, dermatosclerosis, glomerulosclerosis, renal insufficiency, diseases of central nervous system, sensory disturbances, deficiency of memory, depression, amnesia and senile dementia, anxiety neurosis, catatonia, glaucoma and intraocular high tension.

9. The method of claim 7, wherein the compound having diuretic activity is a member selected from the group consisting of amiloride, chlorothiazide, hydrochloride, benzthiazide, ticrynafen, acetazolamide, aminophylline, cyclothiazide, trichloromethiazide, cyclopentiazide, hydrochlorothiazide, methyclothiazide, benthylhydrochlorothiazide, penfluthiazide, ethiazide, hydroflumethiazide, polythiazide, chlophenamide, chlorthalidone, cyclothiazide, bendroflumethiazide, meticrane, tripamide, metrazone, indapamide, quinethazone, furosemide, bumetanide, mefruside, azosemide, ethacrynic acid, sodium ethacrynate, piretanide, spironolactone, potassium canrenoate, quinethazone and triamterene.

10. The method of claim 7, wherein the compound having calcium antagonistic activity is a member selected from the group consisting of diltiazem hydrochloride, teloridine hydrochloride, nicardipine hydrochloride, varnidipine hydrochloride, flunarizine hydrochloride, verapamil hydrochloride, manidipine hydrochloride, cinnarizine, nisoldipine, nitrendipine, nifedipine, nilvadipine, felodipine, nildipine, nimodipine, penidipine and benidipine.